

April 10, 2005

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Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway, HFS-830
College Park, MD 20740-3835

Re: Docket: 2004Q-0151 - Qualified Health Claim: Soy Protein and Cancer

Dear Dr. Shimakawa:

I am writing to protest the proposed soy-protein-prevents-cancer health claim and to request that the FDA hold a public hearing on this matter.

Approval of this health claim would double the sales of soy foods in this country, bringing enormous profits to the soy and food processing industries while putting me, my family and most of the American public at risk.

I am deeply troubled by the prospect of a soy protein/cancer health claim for the following reasons:

- There is no consensus among experts that soy prevents cancer.
- Substantial evidence exists showing that soy can contribute to or even cause cancer, including breast cancer.
- Cancer statistics and epidemiological studies suggest that soy protein consumption might contribute to lower rates of some types of cancer but to higher rates of other types of cancer.
- The plant estrogens (isoflavones) contained in soy protein products can cause thyroid damage, reproductive disorders and other endocrine disruption.
- Soy is one of the top eight allergens, and its increased presence in the food supply would jeopardize the health and lives of many Americans.
- Several subsets of the population are at special risk, including people suffering from hypothyroidism and cancer.

For the above reasons, I urge the FDA to hold a public hearing on soy protein and to reject the proposed qualified soy-prevents-cancer health claim.

Thank you,

Patricia A. Wedegis

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